

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER for: 020702, S018

STATISTICAL REVIEW(S)

Memorandum

Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research

Date: OCT 28 1999
From: David Hoberman, Ph.D., HFD-715
Subject: Lipitor labelling
To: File (NDA# 20-702/SE1-018)

There was no statistical review required for this labelling change. The 25th, 50th and 75th percentiles of percent change from baseline of HDL-C was requested from the sponsor. This request was similar to the one made of Merck for its drug Zocor.

[Signature]
/S/

David Hoberman, Ph.D.

Concur: Dr. Sahlroot *for* *[Signature]*
10-28-99

Dr. Nevius *[Signature]* 10-28-99

cc:
Arch NDA# 20-702
HFD-510
HFD-510/DOrloff, MSimoneau
HFD-715/DHoberman, TSahlroot, DOB2, Chron

APPEARS THIS WAY
ON ORIGINAL